

CLAIMS

What is claimed is:

1. A business method comprising:

a) collecting more than 10 case samples representing a clinical phenotypic state
5 and more than 10 control samples representing patients without said clinical phenotypic state;

b) using a mass spectrometry platform system to obtain mass spectral data in said case samples and in said control samples without regard to a specific identity of at least some of said spectral components;

10 c) identifying representative patterns of markers that distinguish datasets from case samples and control samples; and

d) marketing diagnostic products using said representative patterns wherein said patterns contain more than 15 markers that are represented on output of said mass spectrometer, but the identity of at least some of said more than 15 markers
15 is not known.

2. A business method comprising:

(a) collecting more than 10 case samples representing a clinical phenotypic state and more than 10 control samples representing patients without said clinical phenotypic state;

20 (b) using a mass spectrometry platform system to obtain mass spectral data in said case samples and in said control samples without regard to the specific identity of at least some of said spectral components;

(c) identifying representative patterns of more than 15 polypeptide markers that distinguish datasets from case samples and control samples; and

25 (d) marketing products that use said representative patterns to identify said phenotypic state in additional samples with a disposable device.

3. The method as recited in claims 1 or 2 wherein said products are marketed in a clinical reference laboratory.

4. The method as recited in claims 1 or 2 wherein said marketing step markets kits.

30 5. The method as recited in claim 3 wherein said kits are FDA approved kits.

6. The method as recited in claims 1 or 2 wherein said phenotypic state is a drug response phenotype and further comprising the step of collecting a royalty on said drug.

7. The method as recited in claims 1 or 2 further comprising the step of collecting said samples in collaboration with a collaborator.

8. The method as recited in claim 7 wherein said collaborator is an academic collaborator.

9. The method as recited in claim 7 wherein said collaborator is a pharmaceutical company.

5 10. The method as recited in claim 9 wherein said pharmaceutical company collects said samples in a clinical trial.

11. The method as recited in claim 10 wherein said patterns are used to segregate a drug response phenotype.

10 12. The method as recited in claim 11 further comprising the step of collecting royalties on said drug.

13. The method as recited in claim 11 wherein the step of marketing diagnostic products is performed by the same company as the company performing the identifying step.

14. The method as recited in claims 1 or 2 wherein data from one of said samples are being processed computationally while another of said samples are in said mass spectrometry platform.

15 15. The method as recited in claim 1 wherein said markers are polypeptides.

16. The method as recited in claim 1 wherein said markers are proteins.

17. The method as recited in claims 2 or 15 wherein said patterns contain more than 30 polypeptides that are represented on output of said mass spectrometer, but the identity of at least some of said more than 30 polypeptides is not known.

18. The method as recited in claims 2 or 15 wherein said patterns contain more than 50 polypeptides that are represented on output of said mass spectrometer, but the identity of at least some of said more than 50 polypeptides is not known.

19. The method as recited in claims 2 or 15 wherein said patterns contain more than 100 polypeptides that are represented on output of said mass spectrometer, but the identity of at least some of said more than 100 polypeptides is not known.

20. The method as recited in claims 2 or 15 wherein said samples contain more than 1000 polypeptides that are represented on output of said mass spectrometer, but the identity of at least some of said more than 1000 polypeptides is not known.

21. The method as recited in claims 1 or 2 wherein said marketing step markets a mass spectrometry system used to identify said representative states in patient samples.

22. The method as recited in claims 1 or 2 wherein more than 50 of said cases samples and 50 of said control samples are used.

23. The method as recited in claims 1 or 2 wherein more than 100 of said case samples and 100 of said control samples are used.

24. The method as recited in claims 1 or 2 wherein said diagnostic products use said mass spectrometry platform.

5 25. The method as recited in claims 1 or 2 wherein said step of using a mass spectrometry platform is preceded by the step of preparing said samples on a microfluidics device.

26. The method as recited in claim 25 wherein said diagnostic products are marketed with a disposable microfluidics device, said disposable microfluidics device processing diagnostic samples for use in said mass spectrometry platform.

10 27. The method as recited in claim 25 wherein said microfluidics device comprises a separations device.

28. The method as recited in claim 25 wherein said microfluidics device removes high abundance common proteins.

15 29. The method as recited in claims 1 or 2 wherein said mass spectrometry platform is a time of flight mass spectrometer.

30. The method as recited in claims 1 or 2 wherein said mass spectrometer is a Hadamard time of flight mass spectrometer.

31. The method as recited in claims 1 or 2 wherein said diagnostic products are marketed by a diagnostic partner.

20 32. The method as recited in claims 1 or 2 wherein said phenotype is a drug response phenotype.

33. The method as recited in claims 1 or 2 wherein said phenotype is a drug resistance phenotype.

25 34. The method as recited in claims 1 or 2 wherein said phenotype is a disease stage phenotype.

35. The method as recited in claims 1 or 2 wherein said phenotype is a disease recurrence phenotype.

36. The method as recited in claims 1 or 2 wherein said phenotype is a disease state phenotype.

30 37. The method as recited in claims 1 or 2 wherein said phenotype is a treatment selection phenotype.

38. The method as recited in claims 1 or 2 wherein said phenotype is a disease diagnostic phenotype.

39. The method as recited in claims 1 or 2 wherein said phenotype is a drug toxicity phenotype.

40. The method as recited in claims 1 or 2 wherein said phenotype is an adverse drug response phenotype.

5 41. The method as recited in claim 25 wherein said microfluidics device comprises an electrospray source.

42. The method as recited in claims 1 or 2 wherein said samples contain complex mixtures of polypeptides.

43. The method as recited in claims 1 or 2 wherein revenue is derived from sales of
10 microfluidics devices, mass spectrometers, informatics tools, patterns and/or computer programs for classifying samples and/or from services that provide diagnostic information and/or pattern discovery and/or validation.